

REMARKS

Reconsideration of this Application is respectfully requested.

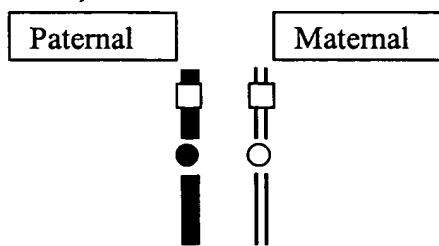
Claims 2-4, 70-73, 75, 80, 82, 84, and 89-91 have been amended and such amendments are supported throughout the specification and in particular Example 1(b) and Example 1(c). No new matter has been added.

Upon entry of the amended, Claims 2-4, 70-73, 75, 80, 82, 84, and 89-91 are pending in the application, with Claims 70, 72, 73, 75, 80, 82, and 89-91 being the independent claims.

Based upon the foregoing Amendments and following Remarks, the applicants respectfully request the Examiner reconsider all outstanding objections and rejections, and that they be withdrawn.

Explanation of the Present Invention

Exhibit 1, herewith attached, is provided to explain how the disclosure of the instant specification yields the claimed parthenogenetically created chromosomally homozygous stem cells. Exhibit 1 is the process of parthenogenetic activation and extrusion of the second polar body followed by self-replication as disclosed in the instant specification. The methods in the specification create stem cells that are homozygous at the chromosomal (genetic) level, not just at a particular locus of a chromosome. The stem cells that result from the ordinary fertilization process between an oocyte and sperm do not yield chromosomally homozygous stem cells because of the contribution from two different sources, a male and a female. It is possible for ordinary fertilization to yield a stem cell that is homozygous for a particular locus on a chromosome,



The boxes represent one area on each chromosome that may be homozygous at that particular locus, but the two chromosomes are not genetically homozygous with respect to the entire chromosome.

but fertilization would never yield a stem cell that is chromosomally homozygous. However, using the methods disclosed in the specification, which provides for a method of parthenogenetic activation, you can obtain chromosomal homozygosity. Further, the activation step occurs after Meiosis I, which is the only time when any crossing-over would occur. Thus, the two homologs of a homologous pair of chromosomes would be almost, if not identical to each other, which cannot be achieved through ordinary fertilization.

Rejection under 35 U.S.C. § 102 (b) – Thomson et al.:

Claims 2-4, 70-73, 75, 80, 82-84, and 89-91 stand rejected under 35 U.S.C. §102(b) as being anticipated by Thomson *et al.* (Science 1998-IDS reference). The Examiner asserts that the Thomson *et al.* reference teaches the isolation and characterization of human embryonic stem cells.

Applicants respectfully traverse this rejection. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Therefore, if a prior art reference does not teach each and every claim element, it does not anticipate the claim.

The Thomson *et al.* reference teaches embryonic stem cell lines derived from human blastocysts using human embryos produced by in vitro fertilization. In contrast to the Thomson *et al.* reference, the present invention claims parthenogenetically created chromosomally homozygous stem cells that are produced from non-embryonic or unfertilized oocytes. As such, the chromosomally homozygous stem cells of the claims are a result of parthenogenetic activation of post-meiosis I diploid germ cells. The instant invention does not use oocytes fertilized by sperm cells, which would give rise to chromosomally heterozygous cells due to the contribution from the oocyte and the sperm. Further, the Thomson *et al.* reference does not teach the homozygosity of the resulting embryonic stem cells. Therefore, the Thomson *et al.* reference

does not anticipate the pending amended claims because it does not teach each and every claim element, namely parthenogenetic activation and chromosomal homozygosity.

Applicants respectfully request reconsideration of this rejection and withdrawal of these grounds of rejection in view of the aforementioned amendments and remarks. The pending claims are not anticipated by the Thomson *et al.* reference.

Rejection under 35 U.S.C. § 102 (b) – Doetschman et al.:

Claims 2-4, 70-73, 75, 80, 82-84, and 89-91 stand rejected under 35 U.S.C. §102(b) as being anticipated by Doetschman *et al.* (J. Embryol. Morph 1985-IDS reference). The Examiner asserts that the Doetschman *et al.* reference teaches the isolation and characterization of mouse embryonic stem cells.

Applicants respectfully traverse this rejection. The Doetschman *et al.* reference teaches the in vitro development of blastocyst-derived embryonic stem cell lines: formation of visceral yolk sac, blood islands and myocardium. However, the Doetschman *et al.* reference does not teach the homozygosity of the resulting mouse embryonic stem cells, nor parthenogenetically activated post-meiosis I diploid germ cells. Further, the embryonic stem cells disclosed by the reference are not pluripotent like the stem cells disclosed and claimed in the instant application. Therefore, the Doetschman *et al.* reference does not anticipate the pending amended claims because it does not teach parthenogenetically created stem cells, or chromosomal homozygosity.

Applicants respectfully request reconsideration and withdrawal of these grounds of rejection in view of the aforementioned amendments and remarks. Applicants submit that the pending claims are not anticipated.

Rejection under 35 U.S.C. § 102 (b) – Evans et al.:

Claims 2-4, 70-73, 75, 80, 82-84, and 89-91 stand rejected under 35 U.S.C. §102(b) as being anticipated by Evans *et al.* (Nature 1981-IDS reference). The Examiner asserts that the Evans *et al.* reference teaches the isolation and characterization of mouse embryonic stem cells.

Applicants respectfully traverse this rejection. The Evans *et al.* reference teaches the establishment in culture of pluripotential cells from mouse embryos derived from pregnant mice. Thus, the resulting cells are created from fertilization of an oocyte by a sperm, which would yield cells that are chromosomally heterozygous. However, the Evans *et al.* reference does not teach the homozygosity of the resulting cells, nor parthenogenetically activated post-meiosis I diploid germ cells. Therefore, the Evans *et al.* reference does not anticipate the pending amended claims because it does not teach each and every element of the claims, namely parthenogenetic activation or chromosomal homozygosity.

Applicants respectfully request reconsideration and withdrawal of these grounds of rejection in view of the aforementioned amendments and remarks. Applicants submit that the pending claims are not anticipated.

Rejection under 35 U.S.C. § 102 (b) – Saito *et al.*:

Claims 2-4, 70-73, 75, 80, 82-84, and 89-91 stand rejected under 35 U.S.C. §102(b) as being anticipated by Saito *et al.* (Dev. Biol. 1992-IDS reference). The Examiner asserts that the Saito *et al.* reference teaches the isolation and characterization of bovine embryonic stem cells.

Applicants respectfully traverse this rejection. The Saito *et al.* reference teaches bovine embryonic stem cell-like cell lines cultured over several passages that were derived from artificially inseminated superovulated cows. Thus, the resulting cells are created from fertilization of an oocyte by a sperm, which would yield cells that are chromosomally heterozygous. Further, the Saito *et al.* reference does not teach the homozygosity of the resulting cells, nor parthenogenetically activated post-meiosis I diploid germ cells. Therefore, the Saito *et al.* reference does not anticipate the pending amended claims because it does not teach each and every element of the claims, namely parthenogenetic activation, or chromosomal homozygosity.

Applicants respectfully request reconsideration and withdrawal of these grounds of rejection in view of the aforementioned amendments and remarks. Applicants submit that the pending claims are not anticipated.

Double Patenting

Claims 2-4, 70-73, 75, 80, 82-84, and 89-91 stand rejected stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 7-14 of co-pending Application No. 10/179,959.

Applicants herewith submit a terminal disclaimer. As such, the double patenting rejection is rendered moot and Applicants respectfully request the rejection be withdrawn

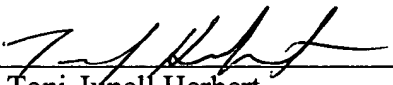
CONCLUSION

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office action and, as such, the present application is in condition for allowance. Applicants wish to expedite the prosecution process and if the Examiner believes, for any reason that personal communication will help expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Response is respectfully requested.

Respectfully submitted,

REED SMITH, LLP

By: 
Toni-Junell Herbert
Reg. No. 34,348

Date: 10/5/05

1301 K Street, N.W.
Suite 1100-East Tower
Washington, D.C. 20005
(202) 414-9200

Explanation of an Embodiment
Parthenogenetically Created Chromosomally Homozygous Stem Cells
U.S. 10/179,959

